

### REMARKS

This is a full and timely response to the non-final Official Action mailed **March 5, 2009** (the “Office Action” or “Action”). Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

#### Claim Status:

Under the imposition of a previous Restriction Requirement, claims 19-44 and 47-49 were withdrawn from consideration and are so marked herein. Withdrawn claim 25 has been cancelled without prejudice or disclaimer. The withdrawn claims have been amended herein consistent with the pending claims. Consequently, upon the allowance of claim 1, claims 19-24, 26-44, and 47-49 will be entitled to rejoinder and allowance. MPEP § 821.04

By the forgoing amendment, various pending claims have also been amended. Further, original claims 6-8 and 16 have been cancelled without prejudice or disclaimer. Thus, claims 1-5, 9-15, 17, 18, 45 and 46 are currently pending for further action.

#### Claim Objections

In the recent Office Action, claims 3, 8, and 15 were objected to because of various informalities. These claims have been carefully reviewed in light of the Examiner's comments.

While Applicant does not necessarily agree that any of these claims contained informalities as filed, the indicated claims have been amended herein to address the issues raised by the Examiner.

Claim 3:

Specifically, with regard to claim 3, the Office Action points out that “a comma appears to be missing between peptides and an antimicrobial in line 2.” (Action, p. 6). Appropriate correction has been made. This amendment clearly has no impact on the scope of the claim and does not narrow the claim in any degree.

Claim 8:

The Office Action further states that claim 8 is “of improper dependent form for failing to further limit the subject matter of a previous claim.” (Action, p. 6). This objection is moot due to the cancelation of claim 8 in the present paper.

Claim 15:

Finally, the Office Action points out that “a comma appears to be missing .between biocide and a viscosity modifier in line 2.” (Action, p. 6). Appropriate correction has been made. This amendment clearly has no impact on the scope of the claim and does not narrow the claim in any degree.

Following these amendments, all the remaining claims are believed to be beyond objection, and notice to that effect is respectfully requested.

35 U.S.C. § 112, first paragraph:

In the recent Office Action, claims 1-18, 45, and 46 were rejected under the written description provision of 35 U.S.C. § 112, second paragraph, for allegedly failing to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. These claims have been carefully reviewed in light of the Examiner's comments.

Claim 1:

The Office Action states that the term “sufficiently low” in claim 1 is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time of the application was filed, had possession of the claimed invention. (Action, p. 7). While Applicant does not necessarily agree, claim 1 has been amended herein to address the issues raised by the Examiner.

Further, the Office Action states that “it is unclear what a ‘naturally occurring oil’ would comprise.” (*Id.*). However, this issue is now moot due to the cancelation of this recitation from claim 1.

Claims 3 and 10:

The Office Action states that the use of “derivatives” with respect to pharmaceuticals in claim 3 and various surfactants in claim 10 “does not describe a sufficient number of species as to convey possession of the entire genus encompassed by derivatives thereof.” (Action, p. 8).

What constitutes a “representative number” [of species within a genus] is ***an inverse function of the skill and knowledge in the art***. Satisfactory disclosure of a “representative number” depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. ***Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces***. For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid

sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species. Cf. *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994).

(MPEP § 2163)(emphasis added).

Thus, Applicant respectfully asserts that one skilled in the relative art (e.g. pharmaceuticals) would readily understand the composition of the derivatives of the various pharmaceuticals of claim 3 and the surfactants in claim 10. Further, one skilled in the relative art would readily understand how to obtain such derivatives. The Office Action has not provided sufficient reasons as to why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed.

Claim 6:

The Office Action states that the specification does not disclose how a removable oil “can be structurally altered or configured to be evaporated.” (Action, p. 8). However, this issue is now moot due to the cancellation of claim 6 in the present paper.

Claim 14:

The Office Action states that “[a] review of the specification did not disclose what types of solvents might comprise a salt.” While Applicant does not necessarily agree that claim 14 was not supported by the specification as filed, claim 14 has been amended herein to address the issues raised by the Examiner under 35 U.S.C. § 112, first paragraph. Support for

the amendment to claim 14 can be found in Applicant's originally filed specification at, for example, paragraph [0031].

Claim 15:

The Office Action states that "the Examiner was unable to locate any species of polymers that Applicant feels would provide adequate written description for the very broad claim of "a non-acrylic polymer." As similarly argued above in connection with claims 3 and 10:

What constitutes a "representative number" [of species within a genus] is *an inverse function of the skill and knowledge in the art*. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. *Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces*. For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species. Cf. *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994).

(MPEP § 2163)(emphasis added).

Thus, Applicant respectfully asserts that one skilled in the relative art (e.g. inks) would readily understand those polymers classified as non-acrylic polymers. Further, one skilled in the relative art would readily understand the application of such non-acrylic polymers in an inkjet composition. The Office Action has not provided sufficient reasons as to why a person skilled in the art at the time the application was filed would not have

recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed.

35 U.S.C. § 112, second paragraph:

In the recent Office Action, claims 1-18, 45, and 46 were rejected under 35 U.S.C. § 112, second paragraph. These claims have been carefully reviewed in light of the Examiner's comments.

Claim 1:

With regard to claim 1, the Office Action states that “[i]t is unclear to the Examiner what oils would fall under a ‘removable oil.’” (Action, p. 9). The Office Action then states that it is unclear how the compositions listed in paragraph [0030] of Applicant’s original application can be considered oils, and that the specification does not clearly redefine the term “oil.” (Action, pp. 9-10). However, this issue is now moot due to the cancelation of this recitation from claim 1.

Further, the Office Action states that “[t]he term ‘edible aqueous solution’ is also unclear to the Examiner” because “[i]t is unclear what additional components are required to be in the solution.” (Action, p. 10). However, this issue is now moot due to the cancelation of this recitation from claim 1.

Finally, with regard to claim 1, the Office Action states that “[i]t would appear that Applicant is referring to a pharmaceutically active agent; however, the Examiner has not been able to locate a definition in the specification.” (Action, p. 10). Claim 1 has been amended to recite a pharmaceutically active ingredient. Support for the amendment to claim 1 can be found in Applicant’s originally filed specification at, for example, paragraphs [0001], [0015],

[0026], [0027], [0032], [0034], [0039], and [0051]. Applicant wishes to point out in paragraph [0015], specifically, that the jettable fluid may contain a pharmaceutically active ingredient, or an oil may contain a solubilized pharmaceutically active ingredient. Thus, the specification supports the recitation of a pharmaceutically active ingredient. Following this amendments, claim 1 is believed to be in compliance with 35 U.S.C. § 112 and notice to that effect is respectfully requested.

Claims 3 and 10:

The Office Action states that the presence of the language “such as” in claim 3 and 10, renders claims 3 and 10 indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. Therefore, claims 3 and 10 have been amended to remove the phrase, “such as.” Following these amendments, claims 3 and 10 are believed to be in compliance with 35 U.S.C. § 112 and notice to that effect is respectfully requested.

Claim 6:

The Office Action states that “it is unclear to the Examiner how removable oil can be configured to be evaporated.” (Action, p. 10). However, this issue is now moot due to the cancelation of claim 6 in the present paper.

Claim 10:

The Office Action states that claim 10 includes the trademark, “pluronic.” Therefore, claim 10 has been amended herein to remove the recitation of the trademark, “pluronic.” Following this amendment, claim 10 is believed to be in compliance with 35 U.S.C. § 112 and notice to that effect is respectfully requested.

Claim 14:

With regard to claim 14, the Office Action states that it is unclear what kind of edible solvent would comprise a salt. Claim 14 has been amended to recite that the solvent further comprises a salt. Support for the amendment to claim 14 can be found in Applicant's originally filed specification at, for example, paragraph [0031]. Following this amendment, claim 14 is believed to be in compliance with 35 U.S.C. § 112 and notice to that effect is respectfully requested.

Claim 17:

The Office Action states that claim 17 is unclear due to the recitation of "varied by varying" what is being altered to vary the release rate of the pharmaceutical. Claim 17 has been amended to recite that "a pharmaceutical release rate of said solution is varied by varying the type of said oil." Support for the amendment to claim 17 can be found in Applicant's originally filed specification at, for example, paragraph [0034]. Following this amendment, claim 17 is believed to be in compliance with 35 U.S.C. § 112 and notice to that effect is respectfully requested.

Claim 18:

The Office Action states that it is unclear if the specific volumes of claim 18 are "in addition to the oil and aqueous solution already present in claim 1 or if it is the oil and aqueous solution of claim 1." (Action, p. 11). Claim 18 has been amended to clarify that the specific amounts of elements are the elements presented in claim 1. Following this amendment, claim 18 is believed to be in compliance with 35 U.S.C. § 112 and notice to that effect is respectfully requested.



Claims 45 and 46:

With regard to claims 45, the Office Action states that the means clauses of these claims do not impart a function specified by the words preceding “means,” and that it is impossible to determine the equivalents of the element. (Action, p. 11). Although Applicant does not agree that the means clauses of these claims fail to impart a function, claim 45 has been amended to recite a means for forming an emulsion. Support for the amendment to claim 45 can be found in Applicant’s originally filed specification at, for example, paragraph [0040]. Following this amendment, claim 45 is believed to be in compliance with 35 U.S.C. § 112 and notice to that effect is respectfully requested.

With regard to claim 46, specifically, the Office Action states that

[T]he word ‘means’ is preceded by the word(s) . . . ‘for stably dispersing’ in an attempt to use a ‘means’ clause to recite a claim element as a means for performing a specific function. However, since no function is specified by the word(s) preceding ‘means,’ it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. (Action, p. 11).

However, Applicant respectfully disagrees.

The phrase “for stably dispersing said emulsion” clearly imparts a function to the word “means.” Further, equivalents of the element may include, for example, a surfactant. (See Applicant’s application, paras. [0026] and [0029]). Therefore, claim 46 is also believed to be in compliance with 35 U.S.C. § 112 and notice to that effect is respectfully requested.

Prior Art: Rejections under 35 U.S.C. §102(b):

1. In the recent Office Action, claims 1-10, 13, 15, 45, and 46 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,004,580 to Backlund et al.

(hereinafter “Backlund”). For at least the following reasons, this rejection should be reconsidered and withdrawn.

Claim 1:

Claim 1 recites:

A jettable solution comprising:

an oil;

an edible surfactant;

an edible aqueous solution; and

a pharmaceutical solubilized into said oil;

in which said oil, said pharmaceutical, said surfactant, and said aqueous solution form a microemulsion;

***in which said jettable solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter such that said solution is configured to be dispensed by jetting through a jetting fluid dispenser.***

(Emphasis added).

Support for the amendment to claim 1 can be found in Applicant’s originally filed specification at, for example, paragraph [0042].

In contrast, Backlund does not teach or suggest a jettable solution in which said jettable solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter such that said solution is configured to be dispensed by jetting through a jetting fluid dispenser. In the amendment of claim 1, the recitations of claim 16 have been incorporated into claim 1. The Office Action fails to address the patentability of claim 16 under either 35 U.S.C. §§ 102 or 103. Thus, the Office Action has failed to prove a prima facie case of anticipation under 35 U.S.C. §§ 102 with regard to claim 1.

It is incumbent upon the Examiner to identify where in the reference each element may be found. Ex parte Levy, 17 U.S.P.Q.2d 1461 (BPAI 1990). Consequently, when the

Examiner fails to identify a claimed element, the Examiner has failed to establish a prima facie case of anticipation. Thus, for this reason alone, the rejection of claim 1 and its dependent claims should be reconsidered and withdraw.

Further, as stated in previous responses, Backlund does not teach or suggest *a jettable solution* in which said jettable solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter *such that said solution is configured to be dispensed by jetting through a jetting fluid dispenser*.

The Office Action states that “[o]n pages 3-4 of the instant specification, jettable is defined as “any material that has properties sufficient to all the material to allow the material to be selectively deposited by any digitally addressable inkjet (sic) material dispenser.” (Action, p. 5). The Office Action then argues that because the Applicant has not specified a viscosity or a particular dispenser, that the rejection is maintained. (*Id.*). However, Applicant respectfully argues that Backlund does not teach a jettable solution or a jettable solution with the specific viscosities and surface tension values as recited in claim 1.

“Section 102 embodies the concept of novelty—if a device or process has been previously invented (and disclosed to the public), then it is not new, and therefore the claimed invention is “anticipated” by the prior invention. . . . *But it does not tell the whole story*. Because the hallmark of anticipation is prior invention, *the prior art reference*—in order to anticipate under 35 U.S.C. § 102—*must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’* *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983).” *Net MoneyIn v. Verisign*, 545 F.3d 1359, 88 U.S.P.Q. 2nd 1751 (Fed. Cir. 2008)(emphasis added).

Backlund teaches “that a gelatinizer and water are added to the microemulsion thereby bringing the microemulsion into a gel form.” (Backlund, abstract). According to Backlund, “[g]els denote soft, *solid or pseudosolid systems* comprising of two or more components one of which is a liquid constituting a major part.” (Backlund, col. 2, lines 53-55). Backlund elsewhere teaches “gelatinizer and water being added to the microemulsion thereby bringing the microemulsion in gel form.” (Backlund, claim 14). “The obtained microemulsion-based gel is moulded into pieces of desired size and shape.” (Backlund, col. 6, lines 47-51).

Thus, because Backlund does not teach or suggest a jettable solution, but instead teaches only embodiments that are solid or pseudosolid gels, under *Net MoneyIn*, Backlund does not disclose those elements “arranged as in the claim.” Specifically, Backlund does not teach a jettable solution, or a jettable solution with the specific viscosities and surface tension values as recited in claim 1.

Claim 1 recites a jettable solution in which said jettable solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter such that said solution is configured to be dispensed by jetting through a jetting fluid dispenser. Clearly, Backlund does not teach or suggest the recitations of claim 1 “arranged as in the claim.”

Finally, Backlund does not teach or suggest a jettable solution in which said jettable solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter such that said solution is configured to be dispensed by jetting through a jetting fluid dispenser. In other words, Backlund does not teach or suggest the a jettable solution with the specific viscosity of less than approximately 5 centipoise or a surface tension approximately between 25 to 60 dynes per centimeter. This is clearly not taught or suggested by Backlund.

“A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). See M.P.E.P. § 2131. Therefore, for at least the reasons explained here, the rejection based on Backlund of claim 1 and its dependent claims should be reconsidered and withdrawn.

Claim 45:

Claim 45 recites:

A jettable solution comprising:

a water insoluble pharmaceutical payload; and  
a means for emulsifying said pharmaceutical payload into a jettable solution,

***in which said means for emulsifying said pharmaceutical payload into a jettable solution is configured to create a jettable solution with a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter such that said solution is configured to be configured to be dispensed by jetting through a jetting fluid dispenser.***

(Emphasis added).

In contrast, Backlund does not teach or suggest a jettable solution comprising a means for emulsifying said pharmaceutical payload into a jettable solution in which said means for emulsifying said pharmaceutical payload into a jettable solution is configured to create a jettable solution with a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter such that said solution is configured to be configured to be dispensed by jetting through a jetting fluid dispenser. As an initial matter, in the amendment of claim 45, the recitations of claim 16 have been incorporated into claim 45. The Office Action fails to address the patentability of claim 16 under either 35 U.S.C. §§

102 or 103. Thus, the Office Action has failed to prove a prima facie case of anticipation under 35 U.S.C. §§ 102 with regard to claim 45.

It is incumbent upon the Examiner to identify where in the reference each element may be found. *Ex parte Levy*, 17 U.S.P.Q.2d 1461 (BPAI 1990). Consequently, when the Examiner fails to identify a claimed element, the Examiner has failed to establish a prima facie case of anticipation. Thus, for this reason alone, the rejection of claim 45 and its dependent claim should be reconsidered and withdrawn.

Further, as stated above, Backlund does not teach or suggest a jettable solution comprising a means for emulsifying said pharmaceutical payload *into a jettable solution in which said means for emulsifying said pharmaceutical payload into a jettable solution is configured to create a jettable solution with a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter such that said solution is configured to be dispensed by jetting through a jetting fluid dispenser.*

The Office Action states that “[o]n pages 3-4 of the instant specification, jettable is defined as “any material that has properties sufficient to allow the material to be selectively deposited by any digitally addressable inkjet (sic) material dispenser.” (Action, p. 5). The Office Action then argues that “the examiner respectfully disagrees for the same reasons as discussed” in connection with claim 1. (Action, pp. 5-6). However, Applicant respectfully argues that Backlund does not teach a jettable solution or a jettable solution with a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter as recited in claim 45.

Again, under *Net MoneyIn v. Verisign*, 545 F.3d 1359, 88 U.S.P.Q. 2nd 1751 (Fed. Cir. 2008), *the prior art reference*—in order to anticipate under 35 U.S.C. § 102—*must not*

*only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’* 545 F.3d 1359, 88 U.S.P.Q. 2nd 1751 (Fed. Cir. 2008)(emphasis added).

Backlund teaches “that a gelatinizer and water are added to the microemulsion thereby bringing the microemulsion into a gel form.” (Backlund, abstract). According to Backlund, “[g]els denote soft, *solid or pseudosolid systems* comprising of two or more components one of which is a liquid constituting a major part.” (Backlund, col. 2, lines 53-55). Backlund elsewhere teaches “gelatinizer and water being added to the microemulsion thereby bringing the microemulsion in gel form.” (Backlund, claim 14). “The obtained microemulsion-based gel is moulded into pieces of desired size and shape.” (Backlund, col. 6, lines 47-51).

Thus, because Backlund does not teach or suggest a jettable solution, but instead teaches only embodiments that are solid or pseudosolid gels, under *Net MoneyIn*, Backlund does not disclose those elements “arranged as in the claim.” Specifically, Backlund does not teach a jettable solution as recited in claim 45.

In contrast to Backlund, claim 45 recites a jettable solution comprising a means for emulsifying said pharmaceutical payload into a jettable solution in which said means for emulsifying said pharmaceutical payload into a jettable solution is configured to create a jettable solution with a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter such that said solution is configured to be configured to be dispensed by jetting through a jetting fluid dispenser. Clearly, Backlund does not teach or suggest the recitations of claim 45 “arranged as in the claim.”

Finally, Backlund does not teach or suggest a jettable solution in which said jettable solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter such that said solution is configured to

be dispensed by jetting through a jetting fluid dispenser. In other words, Backlund does not teach or suggest the a jettable solution with the specific viscosity of less than approximately 5 centipoise or a surface tension approximately between 25 to 60 dynes per centimeter. This is clearly not taught or suggested by Backlund.

Again, “[a] claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). See M.P.E.P. § 2131. Therefore, for at least the reasons explained here, the rejection based on Backlund of claim 45 and its dependent claim should be reconsidered and withdrawn.

Additionally, various dependent claims of the application recite subject matter that is further patentable over the cited prior art. Specific, non-exclusive examples follow.

Claim 46:

Claim 46 recites: “[t]he jettable solution of claim 45, wherein said jettable solution further comprises a means for stably dispersing said emulsified pharmaceutical payload.” The Office Action failed to address the patentability of claim 46 under either 35 U.S.C. §§ 102 or 103. Thus, the Office Action has failed to prove a prima facie case of anticipation under 35 U.S.C. §§ 102 with regard to claim 46.

It is incumbent upon the Examiner to identify where in the reference each element may be found. Ex parte Levy, 17 U.S.P.Q.2d 1461 (BPAI 1990). Consequently, when the Examiner fails to identify a claimed element, the Examiner has failed to establish a prima



facie case of anticipation. Thus, for this reason alone, the rejection of claim 46 should be reconsidered and withdrawn.

2. In the recent Office Action, claims 1-2, 5, 8, 13-15, 45, and 46 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,633,226 to Owen et al. (hereinafter “Owen”). For at least the following reasons, this rejection should be reconsidered and withdrawn.

Claim 1:

Again, claim 1 recites:

A jettable solution comprising:

- an oil;
- an edible surfactant;
- an edible aqueous solution; and
- a pharmaceutical solubilized into said oil;

in which said oil, said pharmaceutical, said surfactant, and said aqueous solution form a microemulsion;

***in which said jettable solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter such that said solution is configured to be dispensed by jetting through a jetting fluid dispenser.***

(Emphasis added).

Support for the amendment to claim 1 can be found in Applicant’s originally filed specification at, for example, paragraph [0042].

In contrast, Owen does not teach or suggest a jettable solution in which said jettable solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter such that said solution is configured to be dispensed by jetting through a jetting fluid dispenser. In the amendment of claim 1, the recitations of claim 16 have been incorporated into claim 1. The Office Action fails to

address the patentability of claim 16 under either 35 U.S.C. §§ 102 or 103. Thus, the Office Action has failed to prove a prima facie case of anticipation under 35 U.S.C. §§ 102 with regard to claim 1.

It is incumbent upon the Examiner to identify where in the reference each element may be found. Ex parte Levy, 17 U.S.P.Q.2d 1461 (BPAI 1990). Consequently, when the Examiner fails to identify a claimed element, the Examiner has failed to establish a prima facie case of anticipation. Thus, for this reason alone, the rejection of claim 1 and its dependent claims should be reconsidered and withdrawn.

Further, Owen does not teach or suggest a jettable solution in which said jettable solution comprises *a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter such that said solution is configured to be dispensed by jetting through a jetting fluid dispenser*. The Office Action states that “[i]t is the position of the Examiner that a liquid would have a viscosity sufficiently low to allow for ‘jetting’ as recited in the claims.” (Action, p. 13).

Owen discloses that “[t]he w/o microemulsions *can be solids including semi-solids, gels, or liquids at room temperature*.” However, Owen does not teach or suggest that such microemulsions may be jetted through jetting fluid dispenser, nor does Owen teach or suggest the viscosities and surface tension values of claim 1.

However, claim 1 recites a jettable solution in which said jettable solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter such that said solution is configured to be dispensed by jetting through a jetting fluid dispenser. This subject matter is clearly not taught or suggested by Owen.

“A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). See M.P.E.P. § 2131. Therefore, for at least the reasons explained here, the rejection based on Owen of claim 1 and its dependent claims should be reconsidered and withdrawn.

Claim 45:

Claim 45 recites:

A jettable solution comprising:

a water insoluble pharmaceutical payload; and

a means for emulsifying said pharmaceutical payload into a jettable solution,

***in which said means for emulsifying said pharmaceutical payload into a jettable solution is configured to create a jettable solution with a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter such that said solution is configured to be configured to be dispensed by jetting through a jetting fluid dispenser.***

(Emphasis added).

In contrast, Owen does not teach or suggest a jettable solution comprising a means for emulsifying said pharmaceutical payload into a jettable solution in which said means for emulsifying said pharmaceutical payload into a jettable solution is configured to create a jettable solution with a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter such that said solution is configured to be configured to be dispensed by jetting through a jetting fluid dispenser. As an initial matter, in the amendment of claim 45, the recitations of claim 16 have been incorporated into claim 45. The Office Action fails to address the patentability of claim 16 under either 35 U.S.C. §§

102 or 103. Thus, the Office Action has failed to prove a prima facie case of anticipation under 35 U.S.C. §§ 102 with regard to claim 45.

It is incumbent upon the Examiner to identify where in the reference each element may be found. *Ex parte Levy*, 17 U.S.P.Q.2d 1461 (BPAI 1990). Consequently, when the Examiner fails to identify a claimed element, the Examiner has failed to establish a prima facie case of anticipation. Thus, for this reason alone, the rejection of claim 45 and its dependent claim should be reconsidered and withdrawn.

Further, The Office Action has failed to address the patentability of claim 45 under either 35 U.S.C. §§ 102 or 103 in view of Owen. Thus, the Office Action has failed to prove a prima facie case of anticipation under 35 U.S.C. §§ 102 with regard to claim 45.

Again, it is incumbent upon the Examiner to identify where in the reference each element may be found. *Ex parte Levy*, 17 U.S.P.Q.2d 1461 (BPAI 1990). Consequently, when the Examiner fails to identify a claimed element, the Examiner has failed to establish a prima facie case of anticipation. Thus, for this reason alone, the rejection of claim 45 and its dependent claim should be reconsidered and withdrawn.

Finally, Owen does not teach or suggest a jettable solution in which said jettable solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter such that said solution is configured to be dispensed by jetting through a jetting fluid dispenser. In other words, Owen does not teach or suggest the a jettable solution with the specific viscosity of less than approximately 5 centipoise or a surface tension approximately between 25 to 60 dynes per centimeter. This is clearly not taught or suggested by Owen.

Again, “[a] claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single

prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). See M.P.E.P. § 2131. Therefore, for at least the reasons explained here, the rejection based on Owen of claim 45 and its dependent claim should be reconsidered and withdrawn.

Additionally, various dependent claims of the application recite subject matter that is further patentable over the cited prior art. Specific, non-exclusive examples follow.

Claim 46:

Claim 46 recites: “[t]he jettable solution of claim 45, wherein said jettable solution further comprises a means for stably dispersing said emulsified pharmaceutical payload.” As stated above, the Office Action failed to address the patentability of claim 46 under either 35 U.S.C. §§ 102 or 103. Thus, the Office Action has failed to prove a prima facie case of anticipation under 35 U.S.C. §§ 102 with regard to claim 46.

It is incumbent upon the Examiner to identify where in the reference each element may be found. *Ex parte Levy*, 17 U.S.P.Q.2d 1461 (BPAI 1990). Consequently, when the Examiner fails to identify a claimed element, the Examiner has failed to establish a prima facie case of anticipation. Thus, for this reason alone, the rejection of claim 46 should be reconsidered and withdrawn.

Prior Art: Rejections under 35 U.S.C. §103(a):

In the recent Office Action, claims 11, 12, 17, and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Backlund in view of “Formulation and Physiochemical Properties of Macro- and Micro Emulsions Prepared by Interracial Ion-pair Formation

between . . . “ to Woo (hereinafter “Woo”). The rejection of claim 11, 12, 17, and 18 should be reconsidered and withdrawn for at least the same reasons given above in favor of the patentability of independent claim 1.

Conclusion:

In view of the foregoing arguments, all claims are believed to be in condition for allowance over the prior art of record. Therefore, this response is believed to be a complete response to the Office Action. However, Applicant reserves the right to set forth further arguments in future papers supporting the patentability of any of the claims, including the separate patentability of the dependent claims not explicitly addressed herein. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed.

The absence of a reply to a specific rejection, issue, or comment in the Office Action does not signify agreement with or concession of that rejection, issue, or comment. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicants expressly do not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03.

If the Examiner has any comments or suggestions which could place this application in better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

DATE: June 5, 2009

/Steven L. Nichols/

Steven L. Nichols

Registration No. 40,326

Steven L. Nichols, Esq.  
Managing Partner, Utah Office  
**Rader Fishman & Grauer PLLC**  
River Park Corporate Center One  
10653 S. River Front Parkway, Suite 150  
South Jordan, Utah 84095

(801) 572-8066  
(801) 572-7666 (fax)